510(k) Summary K073104

SUBMITTER

Submitted on behalf of:

Company Name: **Leonhard Lang GmbH**
Address: Archenweg 56
6020 Innsbruck
Austria
Telephone: ++ 43 / 512 / 33 4 25 7
Fax: ++ 43 / 512 / 39 22 10
Registration Number: 8020045
Owner/0perator Number: 8020045

by: **Elaine Duncan**, MS.M.E., RAC
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: 715-549-6035
Fax: 715-549-5380

NOV 1 6 2007

Contact Person: **Elaine Duncan**
Date prepared: October 31, 2007
Trade Name: Skintact® ECG Electrodes with Conductive Adhesive
(and as also to be offered for sale under various private label tradenames)
Common Name: Disposable ECG Electrodes
Classification Name: Electrocardiograph (ECG) Electrode
Regulation 21 CFR 870.2360
Regulatory Class This device is Class II
Device Panel and Product Code: Cardiovascular: 74 DRX
Reason for 510(k) Submission: change in material: gel

Substantial Equivalence: **Skintact® ECG Electrodes with Conductive Adhesive** are substantially equivalent to the stated predicate devices. The only change between the original **Skintact® ECG Electrodes** and the **Skintact® ECG Electrodes with Conductive Adhesive** is the change in the conducting media gel. Conductive gel electrodes were previously cleared by FDA (3M Red Dot) and the gel has been previously cleared in a submission by the manufacturer.

K023503 Leonhard Lang Skintact® ECG Electrodes with solid adhesive gel
K040249 Leonhard Lang Skintact® radiolucent and MRI-compatible ECG Electrodes
K000690 3M Red Dot Radiolucent Monitoring Electrode with Conductive Adhesive
K000206 Pals Neonatal Pediatric ECG Electrodes, Models PN100 PN200

Description of device: All Skintact® ECG Electrodes are self-adhesive, non-sterile, single use disposable electrodes. The Skintact® ECG Electrodes with Conductive Adhesive are composed of the same materials as the predicate devices by Leonhard Lang except the gel, which is made by AmGel Technologies.

Indications for use: Skintact® ECG Electrodes with Conductive Adhesive have the same indications for use as approved in predicate 510(k)s: *Skintact® ECG Electrodes are designed for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include in particular patient ECG surveillance and ECG diagnosis recording. Skintact® ECG Electrodes are single-use, non-sterile, disposable and are to be used on intact (uninjured) skin.*

Basis for Equivalence: performance testing: Biocompatibility testing was the same as predicate devices and passed ISO 10993 for intact skin. The performance data of Skintact® ECG Electrodes with Conductive Adhesive and the predicate devices (K023503, K040249) met specifications as established in ANSI/AAMI EC12:2000. The shelf life of Skintact® ECG Electrodes with Conductive Adhesive was tested in accelerated aging in the same manner as the predicate devices. .The introduction of the Skintact® ECG Electrodes with Conductive Adhesive *(and as also to be offered for sale under various private label tradenames)* does not introduce new issues of safety or effectiveness and the Skintact® ECG Electrodes with Conductive Adhesive are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2007

Leonhard Lang GmbH
c/o Ms. Elaine Duncan, MSME, RAC
President
Paladin Medical Inc.,
P.O. Box 560
Stillwater, MN 55082

Re: K073104
Skintact® ECG Electrodes with Conductive Adhesive (and various private label tradenames)
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (two)
Product Code: DRX
Dated: October 31, 2007
Received: November 2, 2007

Dear Ms. Duncan:

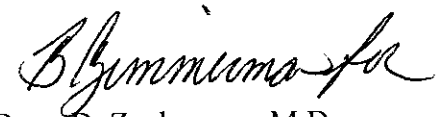
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073104

Device Name: Skintact® ECG Electrodes with Conductive Adhesive

Indications For Use:

Skintact ECG Electrodes are designed for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include in particular patient ECG surveillance and ECG diagnosis recording.

Skintact ECG Electrodes are single use, non-sterile and disposable and are to be used on intact (uninjured) skin.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073104